Award Number: W81XWH-12-2-0022

TITLE: Prehospital Use of Plasma for Traumatic Hemorrhage

PRINCIPAL INVESTIGATOR: Bruce D. Spiess

CONTRACTING ORGANIZATION: Virginia Commonwealth University, Richmond, VA 23298

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Fort Detrick, Maryland 21702-5012

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Bruce D. Spiess, MD, FAHA, Principle Investigator

E-Mail: bdspiess@vcu.edu

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Virginia Commonwealth University
Richmond, VA 23219-1441

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13. SUPPLEMENTARY NOTES

14. There are no significant research findings to report at this time. The VCU Center for Clinical and Translational Research and Technology Services is working to create and review design of media and publications for community notification activities. Standard Operating Procedures (SOP's) are being reviewed and revised as we conduct walk-through scenarios. The plan is to have SOP's formally in place when mock drills take place. Data collection tools are undergoing review by actual users and final touches for this tool are being implemented. Communication is ongoing with DSMB members and Safety Monitor to inform them of progress and plans for trial to begin within the next 4-5 weeks. IRB submission paperwork for approval by the Secretary of the Army and HRPO is being finalized.

15. SUBJECT TERMS: nothing listed

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
					USAMRMC
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			**19b. TELEPHONE NUMBER** *(include area code)*
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Introduction

The contract for our project, Prehospital Use of Plasma for Traumatic Hemorrhage, was awarded June 1, 2012. The greater part of this past year was spent seeking the regulatory approvals required prior to enrolling patients. Approval was granted that allowed for a nurse Project Coordinator under the direct supervision of the PI to oversee completion of the IND and coordinate all facets of the study. The IND was submitted in January 2014 and written approval from the FDA to proceed with the study was received in February 2014. (Appendix 1) With permission to proceed, the FDA suggested a few changes to the IND that were addressed in a follow-up letter. (Appendix 2) Following FDA approval, our next step was to obtain VCUMC IRB approval. The request for VCU IRB approval is submitted and we are currently waiting for written approval from our Internal Review Board and preparing for the Secretary of Army HRPO Approval. The study team is working diligently and will be prepared for study enrollment as soon as all regulatory requirements to proceed are met.

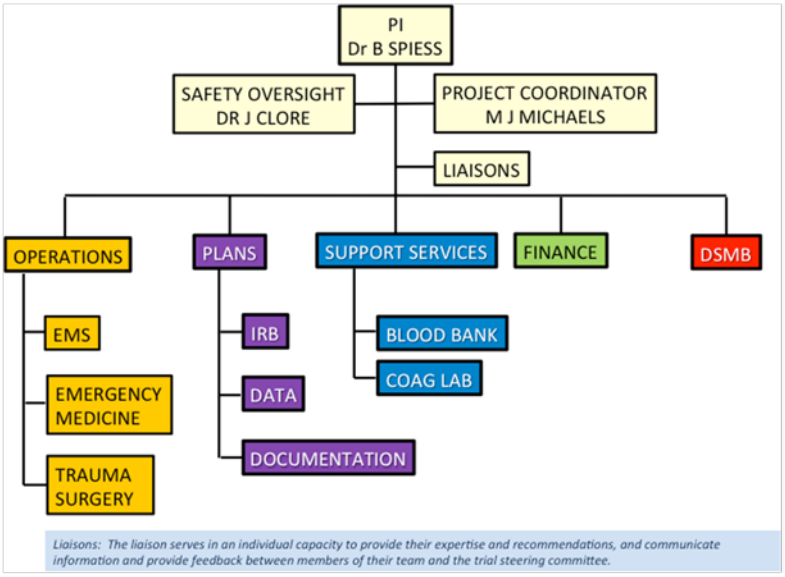
Body

During this reporting period that outlines the past 12 months, several key changes were made to the original study design as recommended and approved by the FDA. These included:

- The primary objective of this study is to compare the 30-day mortality between of TP (Group A thawed plasma products) versus normal saline (NS) infusion at earliest contact administered by trained EMS providers in patients who have sustained severe poly-trauma / major hemorrhage.
- Secondary objectives of this study include: comparing vital signs, lab values such as lactate, total bicarbonate and pH, hemoglobin and hematocrit on arrival at scene, entry to VCU ER, 30 minutes after arrival, 1 hour after arrival and 24 hours after arrival. Coagulation function between these 2 groups will be compared and include fibrinogen, factor V, factor VIII, pT, aPTT, von Willebrand's factor, D-dimer, PFA-100, platelet count, flow cytometry, and lipidome testing (arachidonic acid metabolism, eicosinoids, and prostacyclin expression) at baseline, 30 minutes after arrival, 8 hours after arrival and 24 hours after arrival.
- Rates of multi-system organ failure, renal failure, number of days in the ICU, number of days in the hospital, number of days on a ventilator, number of operations, number of infections, and cumulative utilization of blood products individually will also be compared between these 2 groups.

Plasma will be carried everyday in EMS supervisor vehicles and subjects will be randomized to receive TP or Saline.

Beginning January 2014 a new structure of team reporting and accountability was implemented to facilitate the work that needed to be accomplished in this multi-faceted study. The diagram shown provides a visual of our Team structure. Every aspect of the clinical trial from the moment of subject identification as meeting enrollment criteria to data collection, capture, and evaluation is assigned to a Liaison. The designation of project liaisons is necessary to facilitate coordination and communication between organizational units of the trial, and to achieve the best use and allocation of resources or employment of services of one group by another.



The goal of this structure is to enable trial success by ensuring that the different organizational groups involved in this trial can work together to achieve mutual understanding and unity of effort.

A summary of reports from each Liaison follows:

The PUPTH team **Operations Liaison**, an EMT/PhD researcher, has been instrumental in mapping strategies for patient identification, data collection and task allocation. An annual report summarizing the goals, activities, procedure development and the items to be accomplished follow:
GOALS:

- *Safe and adequate delivery, storage, and handover of plasma from Blood bank to EMS and vice-versa*
- *Seamless and error-free collection of blood samples from patients and delivery to PUPTH personnel*
- *Seamless and error-free chain of communication between EMS and relevant parties (ED, Blood Bank)*

Activities:

- *Designed Powerpoint EMS training course in PUPTH protocol. The training course consists of 50 slides, and includes an introduction to the study, training outline, EMS field protocols (patient inclusion and exclusion criteria, study activation protocol, consent protocol, blood sampling, documentation,*

risks of plasma administration, protocol for transfusion-related adverse reactions), and contact information

- *Training course distributed to EMS agencies for uploading on protected agency sites.*
- *Established checklist system for EMS patient enrollment, consent, blood sampling, data acquisition*

Procedure development:

- *In collaboration with the Coagulation laboratory, development of blood sampling 'kits'.*
- *Ordered all relevant supplies for sample kits (vacutainers, blood sampling accessories, bags, boxes, labels)*
- *Research, identify, and comparison price barcoding systems to streamlining sample tracking and inventory procedures. Ordered all relevant supplies.*
- *Met with RAA for kit oversight, approval, and refinement*

To Complete:

- *PRIORITY ITEM: Establish contact information channels for EMS providers for PUPTH protocol activation (Liaison with ED, MCV Communication/operations)*
- *Establish contact information channels for Biostatistics for PUPTH data collection, randomization (Liaison with ED, MCV Communications/operations)*

Fine-tuning of the protocols and procedures will occur in several planned "walk through" and "table-top" simulations followed by 2 "mock drills" prior to the first patient enrollment.

The PUPTH team **Plans Liaison** submitted the following summary report:

ITEM: Accomplishments

sub-ITEM: Community Consultations.

Prior to the start of the community consultation phase, the data management team, led by Brian Bush of the Department of Biostatistics, designed and created two sets of scannable paper surveys to match the two different formats of community consultation sessions that were to be conducted.

Subsequently, Biostatistics student research assistants (Amanda E. Gentry and Edmund R. Glass) picked up community consultation surveys from the study coordinator. Using a combination of automated scanning and careful checking by eye, Bush, Gentry, and Glass converted the marks and free text on the surveys into an electronic format that was accessible to statistical methods. The resulting data resided in a password-protected database. Subsequently, Jacob Wegelin summarized these data and produced a detailed report of the survey results. The report consists of 37 pages, including 28 tables and 22 statistical graphics. These thoroughly summarize the community consultation responses. (Appendix 3)

To produce the data summary and report for the community consultations, Jacob A. Wegelin (Department of Biostatistics) wrote approximately 2300 lines of code in the R language for statistical computing. (A small portion of the code was written by student research assistants under Dr. Wegelin's close supervision.)

[Citation: R Core Team (2013). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. ISBN 3-900051-07-0, URL http://www.R-

project.org/.] As a consequence of Dr. Wegelin's coding, every table, every scalar, every graphic, every date, every cross-reference to a page number or a section number, was generated automatically from the community consultation database.

These custom scripts provided a means by which accuracy of the report could be confirmed and any updates to the database were incorporated into the report, without danger of introducing typographical or copying errors. sub-ITEM: IND resubmission, December 2013 In support of the resubmission of the IND (Investigational New Drug) application to the FDA, Jacob Wegelin composed a new data analysis section. This document provides, in particular, a detailed graphical and verbal explanation of the following: The way in which the methods of Farrington and Manning and of O'Brien and Fleming will be implemented to simultaneously (1) estimate power and sample size, (2) plan and conduct interim tests, and (3) control type one error at 5%. sub-ITEM: Data management for study data Brian Bush, Edmund Glass, and Zachary Martin collaborated with colleagues at the University of Colorado who are conducting the COMBAT study. We studied their information-gathering approach and we implemented shared definitions where feasible, with the goal of supporting future information pooling.

In the PUPTH catchment area, our team initiated meetings with individuals who will gather data for PUPTH, especially EMS and coagulation lab personnel, to facilitate accurate and efficient data gathering.

In addition, we have conducted the first meeting in which we have led the investigators through analysis questions on which the system for data collection will be largely based.

Throughout this process, we are using a continuous improvement methodology to build our study data dictionary. Like our colleagues at the University of Colorado, we are primarily implementing our data collection in the widely accepted web-based REDCap data management system.

ITEM: Reportable outcomes.

As part of the IND resubmission, Dr. Wegelin designed and implemented an innovative graphical illustration of the methods of Farrington and Manning and of O'Brien and Fleming. Although these methods are well known, we are unaware of any previous instance where this kind of graphic has been employed in the illustration of these methods.

Staff of VCU Health System's Blood Bank in collaboration with the PI satisfactorily addressed all questions pertaining to the blood bank that were raised by the FDA after the IND submission (Appendix 4).

The **Support Services Team Liaison** submitted the following report:

The Coagulation Lab is prepared to be staffed 24 hour/day to run study patient lab samples. All instrumentation is in place.

Blood Bank protocols can be found in Appendix 6 of the IND. Staff of VCU Health System's Blood Bank in collaboration with the PI satisfactorily addressed all questions pertaining to the blood bank that were raised by the FDA after the IND submission (Appendix 4).

The refrigerators ordered for the storage of plasma are currently in the VCUMC blood bank undergoing required quality control testing. SOP for stocking and exchange of plasma are in place. The Liaison is currently working on 2 goals: 1. Producing an educational video to be included as part of the required EMS training on the safe handling of plasma, 2. As walk-throughs are carried out,

a continious evaluation will be ongoing for ways to improve flow / exchange of plasma between blood bank and EMS providers.

Key Research Accomplishments

There are no key research accomplishments to report at this time. We will continue to work with the VCU IRB and then the HRPO for regulatory approvals to continue the study and anticipate that enrollment of patients will begin in July 2014.

Reportable Outcomes

There are no reportable outcomes at this time.

Conclusion

In retrospect, this has been a year full of challenges in addressing the necessary regulatory guidelines prior to initiating such an important clinical study. We are still engaged in the IRB process and anticipate that completion within the next month. EMS training is scheduled, procedures are in place, supplies ordered and mock drills are being planned for. We feel confident that we will be ready for study enrollment as soon as all regulations and requirements are met and permissions received. Communications and a Meeting were held with a representative from the VCU IRB to review the newest regulatory guidelines issued from the **DOD Protection of Human Subjects and Adherence to Ethical Standards**. **NUMBER 3216.02**

References

No references at this time.

Appendices

(See Next Page)

Appendix 1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448

February 28, 2014

Our Reference: IND 15910

Virginia Commonwealth University
Attention: Bruce Spiess, MD
Department of Anesthesiology
Room B1-015B
Sanger Hall
1101 East Marshall Street
PO Box 980695
Richmond, VA 23298

Dear Dr. Spiess:

We have reviewed your investigational new drug application (IND) for Pre-Hospital Use of Plasma for Traumatic Hemorrhage (PUPTH) with exception to informed consent under 21 CFR 50.24 and your study may proceed.

However, we have the following comments:

1. With respect to the protocol:

    a. Please consider including 24 hour mortality as a secondary endpoint.

    b. Please add time from EMT arrival at the scene to arrival in the ED in the CRF.

2. With respect to the proposed statistical analysis plan:

    a. The method stated in Farrington and Manning's paper is for testing the null hypothesis in which the treatment and control groups are assumed to differ in a prescribed magnitude. However, it appears the protocol proposes to test the null hypothesis that the two groups are identical, so that the Farrington and Manning method does not apply. Please clarify the primary hypothesis by including a clear statement of the null and the alternative hypothesis in a mathematical format. Please also revise the protocol so that the proposed hypothesis and testing method are consistent.

    b. Please provide detailed formula or method on how to calculate the test statistics to be compared to the O'Brien-Fleming stopping thresholds. In addition, we are

unable to verify the thresholds proposed in the protocol (Stage 1: ±3.49; Stage 2: ±2.46; Final: ±2.00). Please also provide the detail on how you obtained them.

c. You plan to conduct the first interim analysis for early efficacy with a sample size of 35 subjects per arm. We are concerned that you may not have interpretable results from the analysis due to the small sample size. We recommend that you conduct the first interim analysis for early efficacy at a later stage. In addition, we recommend that the DSMB monitor the safety data more often than three times during the study.

d. Please provide an explanation/justification for the choice of values used for the sample size calculation: 24% mortality in the saline group and 9.6% in the plasma group.

e. Please include a missing data section in your protocol. This section should include details regarding how missing data will be handled in statistical analyses, an estimate of the amount of missing data anticipated, and an outline of steps that will be taken in trial conduct to minimize the amount of missing data.

f. Please define different analysis sets (e.g.: full analysis set based on the intent-to-treat principle, evaluable analysis set, per protocol set) in the protocol, and clearly state which set will be used for the primary and secondary analyses. We recommend that the primary analysis be conducted based on all randomized subjects and sensitivity analysis be conducted on a per protocol treated set.

g. Please include details on any planned subgroup analyses and how the analyses will be performed. Specifically, please include subgroup analyses by presence or absence of coagulopathy at presentation, injury type, age, race and gender as well as provide p-values as part of the exploratory analysis results.

h. We recommend developing a detailed statistical analysis plan for the secondary endpoints, including the models to be used and the covariates to be included for each endpoint.

i. You state that the DSMB may recommend stopping if strong trends exist in secondary efficacy outcomes of the study. We strongly recommend that you do not stop the study early to declare success for efficacy based on the outcomes of the secondary efficacy endpoints.

j. Please provide in the protocol the details for the DSMB charter, such as the frequency of DSMB meetings. Please refer to the *Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees* for details on how to modify the DSMB charter.

3. With respect to Community Education, on page 47 of the redline strike out version of the protocol submitted on February 25, 2014, please revise the sentence, "The Community Consultation plan-------" to the "Public Disclosure plan ------."

4. With respect to the Consent Form, Community Consultation and Public Disclosure, please note that your IRB must review and approve any revisions that have been made to the above documents prior to the initiation of the study.

5. With respect to Blood Banking:

    a. Please clarify how TP with low titers of anti-B will be identified to ensure these products are issued to the ambulances.

    b. Please clarify whether the transfusion subjects' blood group will be included in the records so it is available for later review during transfusion reaction investigations.

    c. Several steps in SOP: PUPTH Study Quality Control Protocols contain the abbreviation "TBD", e.g., "TBD" appears under Step A2.00 – Reading/Recording Temperatures. Please define the acronym TBD and indicate the specific procedures to be followed when reading the temperatures and when these procedures will be completed, i.e., will the procedures be completed before they are used to train EMS supervisors?

    d. SOP: Assigning, Issuing, and Returning PUPTH Study Plasma discusses the use of a "bag tag." Please define "bag tag" and clarify why it will be used when all the information for the tie-tag is already included on the container label.

If you have any questions, please contact the Regulatory Project Manager, Sonday L. Kelly, MS, RAC, at (301) 827-6162.

Sincerely yours,

For Jay S. Epstein, MD
Director
Office of Blood Research and Review
Center for Biologics
Evaluation and Research

Appendix 2

Virginia Commonwealth University
Department of Anesthesia
PO Box 980695
Richmond, VA 23298-0695
Phone: 804-828-2267 (office)
E-mail: bdspiess@vcu.edu

April 21, 2014

Department of Health and Human Services
Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20857

Re: IND #15910, Investigational new drug application for Pre-Hospital Use of Plasma for Traumatic Hemorrhage (PUPTH).

Dear Reviewers:
Thank you for the guidance and feedback you provided with respect to our protocol. With your permission we have proceeded with the next set of requirements for the PUPTH clinical study and are currently awaiting a response from the Internal Review Board at VCUMC before beginning the next phase.
We want to share with you our plan of action to the comments made in the letter dated February 28, 2014.

1. With respect to the protocol:
    a. We will add 24hour mortality to the list of secondary endpoints for analysis.
    b. Our data will contain the time of EMT arrival and time of arrival in the ED. Using software, the latter will be subtracted from the former to obtain the elapsed time.
2. With respect to the proposed statistical analysis plan:
    a. In our revised protocol we will clarify these points
    b. In our revised protocol we will clarify these points also
    c. Our sample size and interim analysis are based on our belief that we can enroll about 70 study participants per year. Accordingly, our total planned sample size for three years is 210. We feel that we should perform an interim check about once a year, and consequently the first interim check is scheduled to take place after we have enrolled 35 participants in each arm. The second interim analysis will take place after we have 70 per arm. With regards to monitoring safety

data by the DSMB, our charter for the DSMB for the PUPTH trial strongly recommends at least twice yearly meetings and additional meetings as needed.

ORGANIZATION OF DSMB MEETINGS	
Expected frequency of DSMB meetings	It is recommended that the DSMB meet at least twice yearly and will otherwise depend on the wishes of the DSMB and needs of the trial office will be considered when planning each meeting.
Meeting format	Meetings will be by teleconference, with face-to-face meetings scheduled at the discretion of the DSMB and PI. The PI should try to attend in person if the DSMB requests their presence. Arrangements will be made for an early meeting, before many main outcome measure events have been accrued**.** This gives a "test run" for the DSMB decision-making process, and a test run for report production.

d. We will explain in more detail the basis for these two mortality rates.
e. We will include a missing data section in the revised protocol.
f. In the revised protocol, we will define the analysis sets.
g. We plan to include more details on subgroup analyses in the revised protocol.
h. We plan to add details and specifics on the analysis of secondary endpoints to the protocol.
i. We agree.
j. The DSMB charter will be included as an appendix. This is the reference we have used thus far; however, we will review the reference you suggested.

[1] Schultz KF, Altman DG, Moher D, CONSORT group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomized trials. BMJ 2010;340:c332doi: 10.1136/bmj.c332; BMJ 340: 698-702, 2010

3. With respect to community education, will make the change from Consultation plan…to Public Disclosure plan…as suggested.
4. It is understood that the VCU IRB must approve any revisions to the Consent form, Community Consultation and Public Disclosure forms prior to the initiation of the study.
5. With respect to blood banking:
   a. Please clarify how TP with low titers of anti-B will be identified to ensure these products are issued to the ambulances.

- All thawed units will have a titer performed against reagent B-cells to ensure that the titer is not greater than 100. If the units are found to have a titer 100 or greater, they will not be used for the study and additional units will be thawed. Once testing has been completed, these units will be tagged and prepared for issue to the EMT Supervisors when needed.

- Procedure:

- Heat seal to create a segment from the integral tube attached to the unit (if segments are not already available).
- Remove the plasma from the segment and add to a test tube that is labeled with the unit number from the unit of plasma.
- Mix the contents of the test tube
- Add 1mL of normal saline to a test tube
- Remove 10uL of saline from the test tube (leaving 990uL)
- Remove 10uL of plasma and add to the test tube containing the saline and is labeled with the correct unit number.
- Mix the contents of the test tube
- Add two drops of the diluted plasma to one drop of known reagent B-cells
- Mix
- Spin in centrifuge for 15 seconds
- Read for agglutination macroscopically
- If agglutination is present, the unit will be excluded from use in the study.

b. Please clarify whether the transfusion subjects' blood group will be included in the records so it is available for later review during transfusion reaction investigations.

- All study subjects' blood typing results will be placed in their electronic medical record (Cerner Millennium) upon completion of testing. This information will be available for review by all authorized personnel.

c. Several steps in SOP: PUPTH Study Quality Control Protocols contain the abbreviation "TBD", e.g., "TBD" appears under Step A2.00 - Reading/Recording Temperatures. Please define the acronym TBD and indicate the specific procedures to be followed when reading the temperatures and when these procedures will be completed, i.e., will the procedures be completed before they are used to train EMS supervisors?

- TBD: Is defined as "to be determined"

- The temperature device will meet all FDA regulations and AABB standards for temperature monitoring of blood and blood products. This includes continuous monitoring and recording of the temperature.

- The temperature recording devices will have alarm settings that will sound if the temperature of the plasma storage device comes within 0.5 degrees Celsius of either the low or high temperature settings.

- Temperature indicators, that change color if a unit exceeds the maximum allowable temperature, will also be used alongside the temperature

monitoring devices to ensure all units were continuously maintained at appropriate temperatures.

- All procedures will be finalized once the final temperature-monitoring device has been purchased and validated. Part of the validation procedure is to update the applicable SOPs.

- All procedures will be completed and approved by the study principal investigator or designee prior to beginning the study.

- This section must remain TBD until such time the temperature monitoring devices are purchased and all of the manufacturer's instructions can be incorporated into the procedure.

d. SOP: Assigning, Issuing, and Returning PUPTH Study Plasma discusses the use of a "bag tag." Please define "bag tag" and clarify why it will be used when all the information for the tie-tag is already included on the container label.

- "Bag tag" is the VCU Medical Center term for tie-tag. "Bag tag" and "tie tag" are one in the same and the information contained on each is the same.

If you have any questions, please contact the PUPTH Study Project Coordinator, Mary Jane Michael, RN, MS, at 804-828-5599 or mmichael@vcu.edu

Sincerely yours,

Bruce D. Spiess, MD, FAHA
Professor Anesthesiology and Emergency Medicine
VCU Medical Center and VCURES
PO Box 980695
1101 East Marshall Street
bdspiess@vcu.edu

Appendix 3

Summary of PUPTH Community Consultation Surveys

Amanda E. Gentry
Edmund R. Glass
Brian Bush
Jacob A. Wegelin
Department of Biostatistics
Virginia Commonwealth University

January 29, 2014

Contents

1 Preface

This document summarizes the surveys obtained from community consultation sessions conducted by the PUPTH research team at Virginia Commonwealth University.

After community consultations had been conducted and surveys gathered, the biostatistics team of PUPTH picked them up from the study coordinator. We converted answers marked by hand, on paper, into an electronic format that was accessible to statistical methods. Then we summarized the data and produced this report.

Surveys were collected in 23 sessions between 2013-05-29 and 2013-11-20. Surveys were either "group administered" or "self administered." A total of 711 surveys were returned: 252 "group" and 459 "self."

We start by summarizing the cover sheets, one for each session: section 2 starting on page 3.

Next, we go through the variables that can be summarized quantitatively. We summarize them both in graphic and tabular format, in the order in which they appeared in the surveys. Two main types of such variables were obtained:

- **Mutually exclusive option**, nominal variables where only a single answer is permitted;
- **All-that-apply option**, where the community member was invited to "bubble in" potentially several options.

We signal the difference between these variables in two ways:

- The graphic looks different.
- The first row of the table states whether it is a **Mutually exclusive option** or an **All-that-apply option**.

Of these variables, 2 appeared in "self" but not in "group," and we summarize them in section 3, which starts on page 7.

The rest are identical in "group" and "self", and are summarized in section 4 starting on page 9.

We make no attempt to contrast the answers on "self" surveys with the corresponding answers on "group" surveys. Instead, we combine the results from both types of surveys, so that a single, consolidated summary is presented for each variable.

Finally, we give in full the answers to free text variables: from the "group" surveys in section 5 starting on page 27; from the "self" surveys in section 6 starting on page 32.

This document ends at page 36.

This preface last Modified: Wed 29 Jan 2014 06:52:54 PM EST

2 Cover sheets

sessionid	date	presenters	type	attendance	Number of surveys	zip	title	location
101	2013-05-29	Duane	Group	45	26	23298	Trauma PCC Meeting	Main Hospital. 1st Floor Learning Center
201	2013-06-10	Han, Katzen	Self	80	60	23298	VCUHS display 201	Gateway - just outside PACB Clinic Waiting Area
102	2013-06-12	Katzen	Group	16	11	23298	ED Leadership Group Mtg	VCUHS - North Hospital - 8th floor library
202	2013-06-19	Han, Katzen	Self	88	64	23298	VCUHS Display 202	Gateway - 1st Floor Lobby
203	2013-06-24	Han, Katzen	Self	87	61	23298	VCUHS Display 203	Gateway - 1st Floor near PACB
103	2013-06-26	Kurz	Group	18	7	23298	VCUHS Emergency Dept. Faculty Staff Mtg 103	VCUMC, Main Hospital, 1st Floor, Faculty Dining Room
104	2013-07-11	Katzen, Spiess	Group	12	7	23223	GRIP Partners Mts 104	East District Family Resource Center, 2405 Jefferson Ave., Richmond VA
105	2013-07-22	Katzen, Ornato	Group	17	15	23220	Public Meeting 105	Richmond Ambulance Authority (RAA), classrooms A and B, 2400 Hermitage Rd., Richmond VA
204	2013-07-28	Han, Katzen	Self	98	67	23223	Creighton Court Community Day	2150 Creighton Rd., Richmond
205	2013-08-17	Katzen	Self	75	57	23223	Richmond Faith Leaders Partnership - Whitcomb Court Community Day	2020 Anniston St, Whitcomb Ct., Richmond
206	2013-08-18	Han, Katzen	Self	108	81	23223	Mosby Court Community Day	1543 Coalter St, Richmond

106	2013-08-26	Ornato	Group	55	31	23223	Neale St/Watts Area Neighborhood Watch	Eastern Henrico Recreation Center, 1440 N Laburnum Ave (covers 23222 also)
107	2013-08-27	Kurz	Group	19	16	23075	North Airport Drive Civic Association	Fire Station 3 training room, 1310 E Washington St, Highland Springs (covers 23150 also)
108	2013-09-09	Aboutanos, Katzen	Group	51	38	23222	East Highland Park Neighborhood Watch	Glen Lee Elementary School (covers 23229 and 23223 also)
109	2013-10-08	Katzen, Ornato	Group	31	23	23231	Varina Ruritan Club	8081 Recreation Rd, Henrico
110	2013-10-10	Katzen, Spiess	Group	18	10	23225	Westover Hills Neighborhood Assoc.	Westover Hills United Methodist Church, 1705 Westover Hills Blvd
111	2013-10-17	Spiess	Group	26	7	23238	Lakeside Methodist Neighborhood Watch	Lakeside United Methodist Church, 233 Hilliard Rd
207	2013-10-19	Katzen	Self	300	69	23224	Imagine Festival (City of Richmond Office of Multicultural Affairs)	Broad Rock Park, 4802 Warwick Road, Richmond 23224
112	2013-11-11	Katzen, Spiess	Group	30	1	23219	City Council (Informal Agenda)	Council Chambers, 900 E Broad St, 2nd floor
113	2013-11-11	Katzen, Spiess	Group	21	14	23060	Wyndham Neighborhood Association	Wyndham Swim and Racket Club, 6401 Wyndham Dr., Glen Allen (Henrico)
114	2013-11-12	Katzen, Spiess	Group	20	9	23224	Oak Grove Civic Association	Kids First Child Care Center, 1000 Jefferson-Davis Hwy, Richmond
115	2013-11-19	Katzen	Group	52	29	23227	Bellevue Civic Association	Linwood Holton Elem. School,1600 W Laburnum Ave., Richmond
116	2013-11-20	Katzen, Spiess	Group	20	8	23219	Education and Human Services Committee of Richmond City Council	City Hall, 900 E Marshall St, Richmond
	Total			1287	711			

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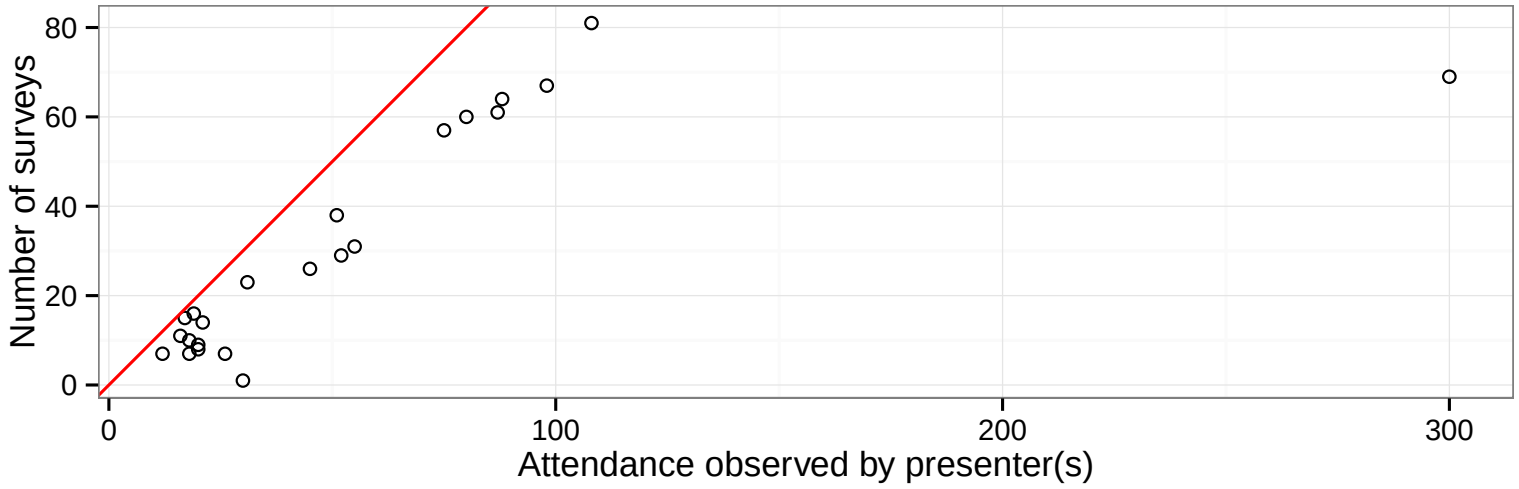
Attendance vs. numbers of surveys returned, by session



This graphic displays the relationship between the number of people reported by the presenters and the number of surveys obtained. The red line shows where the two variables would equal each other. Session 207 is an outlier, as discussed here by Judy Katzen in an email of `2014-01-22-0706` timestamp:

> Unlike other displays at outside venues, the area was a huge public park (i.e. the others were at community centers within public housing) with playing fields, several parking areas around the perimeter. With the weather, time of year (in the fall vs in the summer) and the physical layout of the public park in comparison to the events at the community centers in housing projects, there was not as much "encouragement" for attendees and other vendors to come over to where we were.
>
> The Imagine Festival was held on a cold, rainy October Day. While at other displays, where all "vendors" were (relatively) close together and we could see everyone who was in attendance, this event had us spread all over a very large area. We were not able to see everyone who was there - no they to see us unless they specifically came over to our display. Most attendees to the festival stayed by the stage so they could watch (mostly) their family members perform or were on the playing fields (e.g. there was a soccer game on that field and informal basketball and football in other areas) and left shortly after their "event" (i.e. they didn't come by where we were). Parking was spread around many lots along the perimeter of the park and the one near us was one of the smaller lots. While we had a decent spot - by the only food vendor - not a lot of people came by there either and many who did were walking through (wouldn't even look in our direction).

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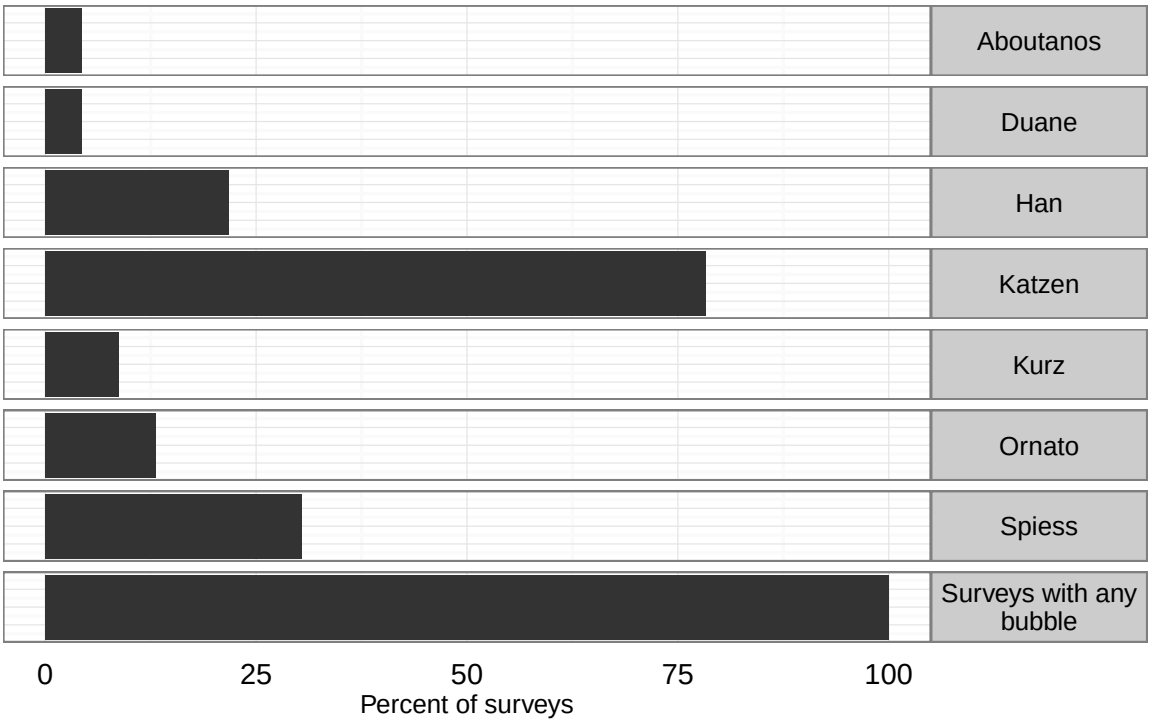
Presenter(s)



Count	All-that-apply option
1	Aboutanos
1	Duane
5	Han
18	Katzen
2	Kurz
3	Ornato
7	Spiess
23	Surveys with any bubble

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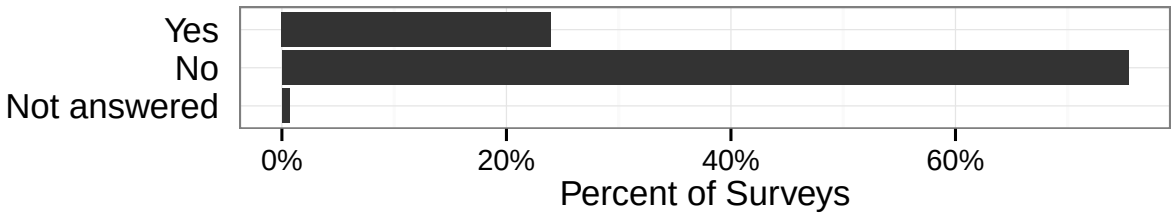
3 Variables in "self" but not "group" surveys

Have you ever participated in a medical research study?



Mutually exclusive option	Count
Yes	110
No	346
Not answered	3
Total	459

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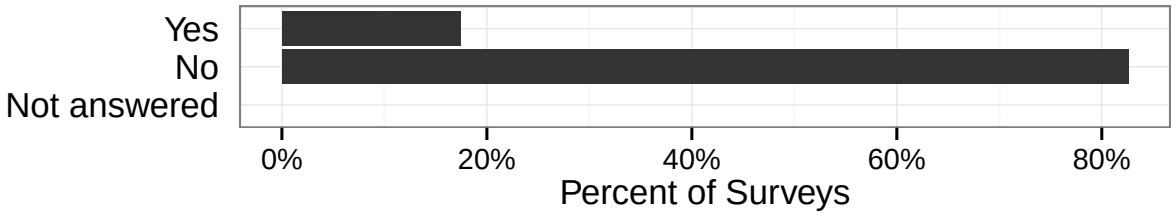
Have you ever given permission or signed a consent form for someone else to participate in a research study?



Mutually exclusive option	Count
Yes	80
No	379
Not answered	0
Total	459

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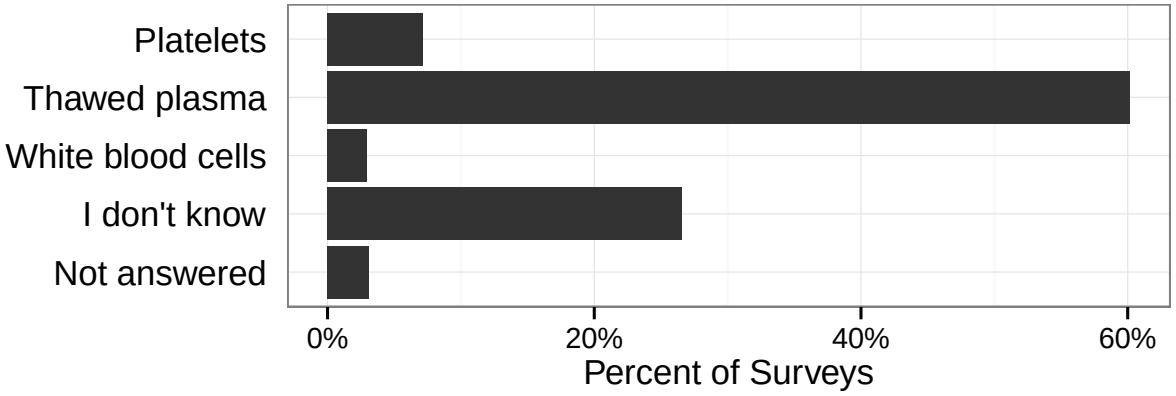
4 Variables in common between "group" and "self" surveys

This study involves receiving a component of blood before reaching the hospital. What component is given? (Bubble only ONE)



Mutually exclusive option	Count
Platelets	51
Thawed plasma	428
White blood cells	21
I don't know	189
Not answered	22
Total	711

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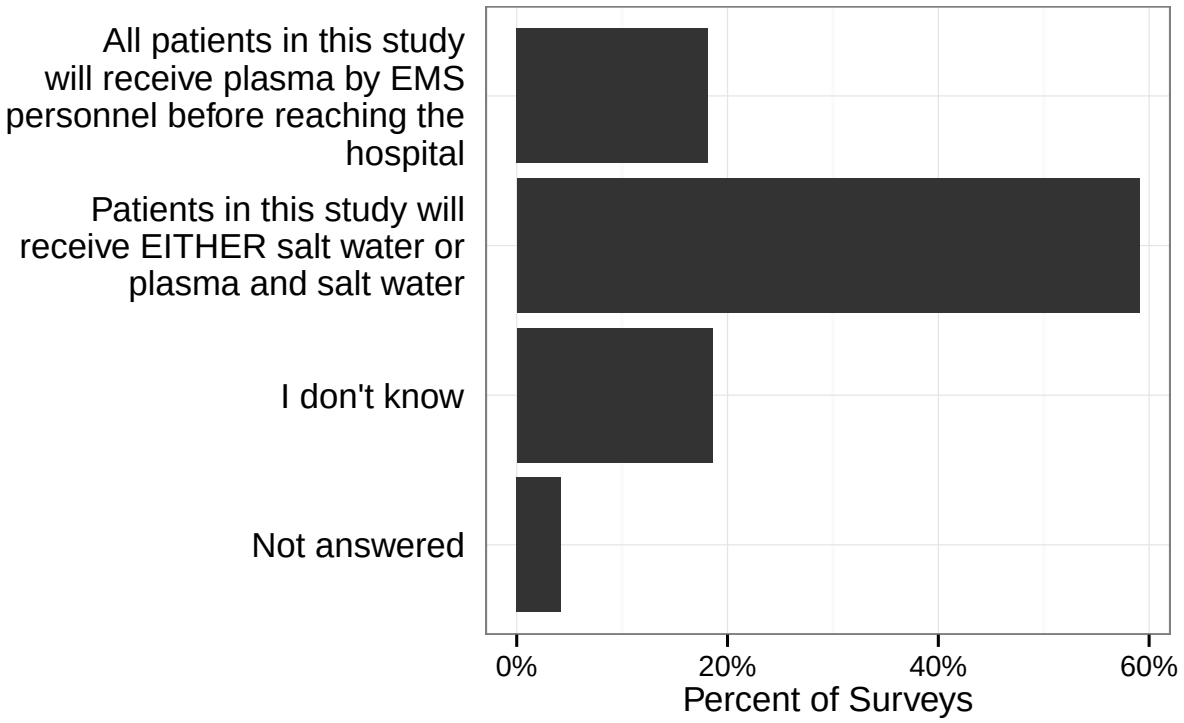
In addition to standard medical care by EMS personnel for trauma patients, which one of the following statements below is true about what type of treatment patients will receive if they are enrolled in the Plasma study? (Bubble only ONE)



Mutually exclusive option	Count
All patients in this study will receive plasma by EMS personnel before reaching the hospital	129
Patients in this study will receive EITHER salt water or plasma and salt water	420
I don't know	132
Not answered	30
Total	711

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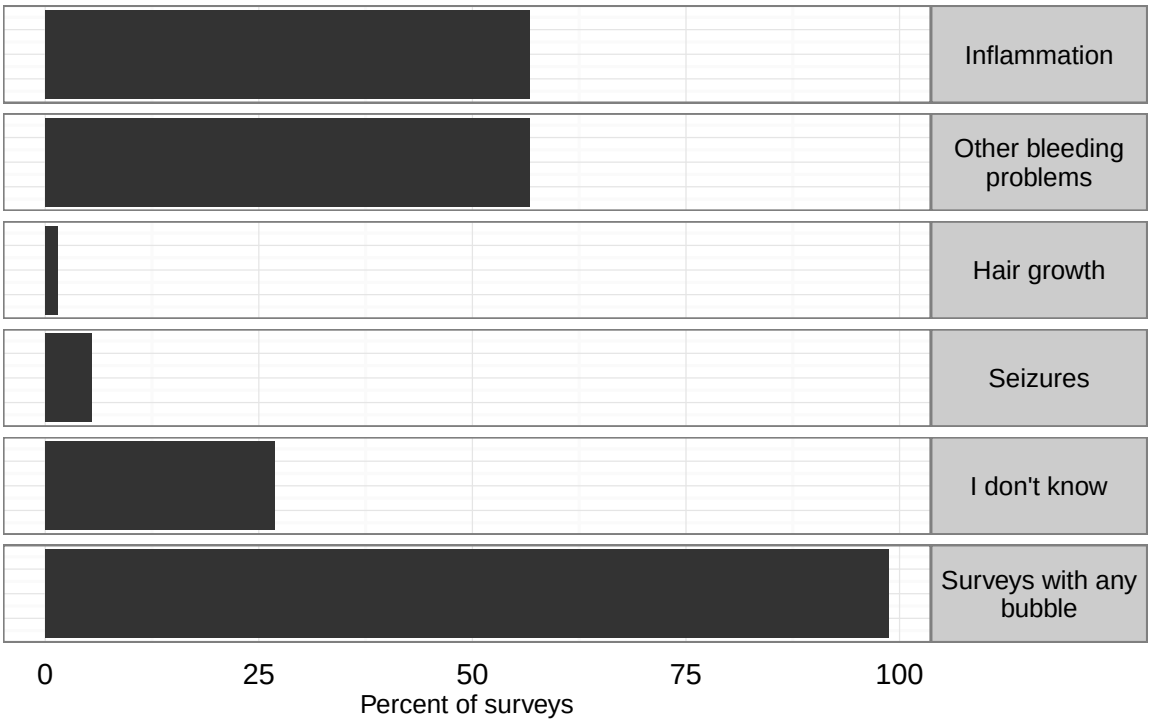
Which of the following are possible risks, or side effects, of receiving Plasma prior to the hospital? (Bubble ALL that apply)



Count	All-that-apply option
403	Inflammation
403	Other bleeding problems
10	Hair growth
39	Seizures
191	I don't know
702	Surveys with any bubble

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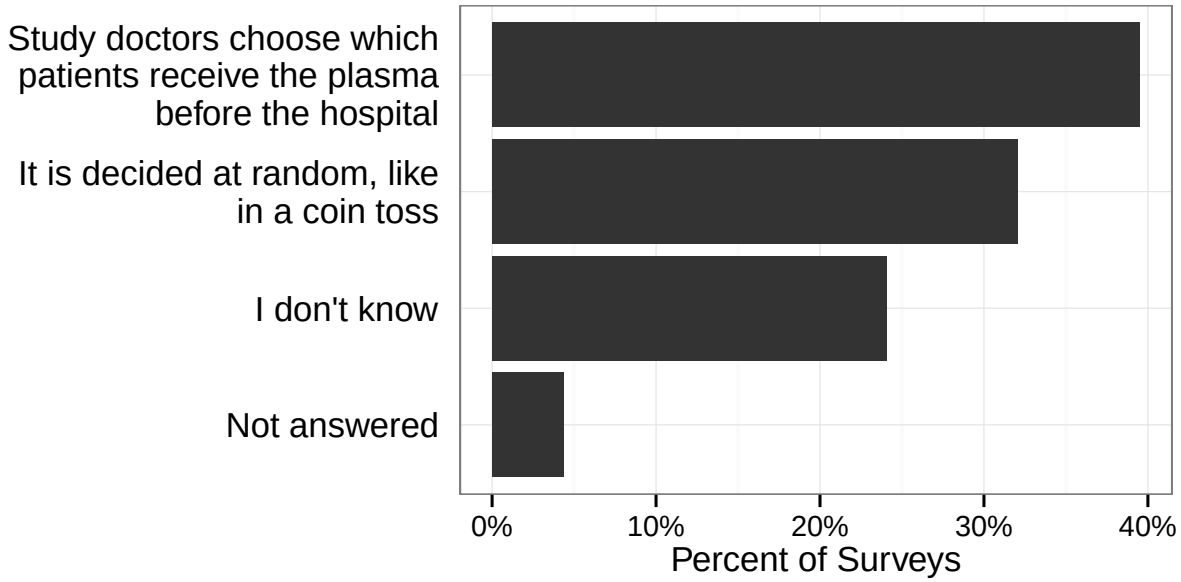
Not all trauma patients included in the Plasma study will be given plasma by EMS personnel. How is it decided which treatment patients receive? (Bubble only ONE)



Mutually exclusive option	Count
Study doctors choose which patients receive the plasma before the hospital	281
It is decided at random, like in a coin toss	228
I don't know	171
Not answered	31
Total	711

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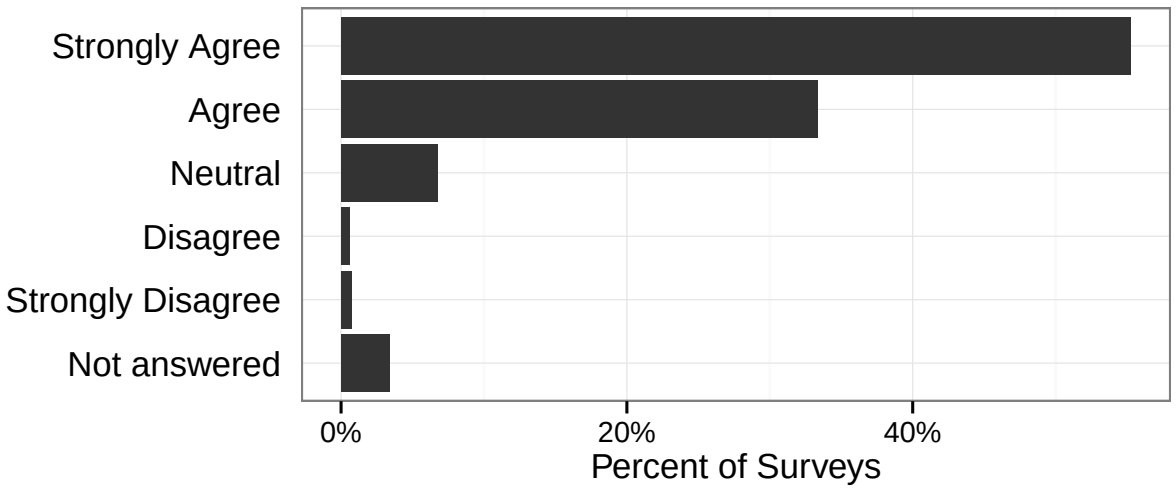
The Plasma study is an important study to do.



Mutually exclusive option	Count
Strongly Agree	393
Agree	237
Neutral	48
Disagree	4
Strongly Disagree	5
Not answered	24
Total	711

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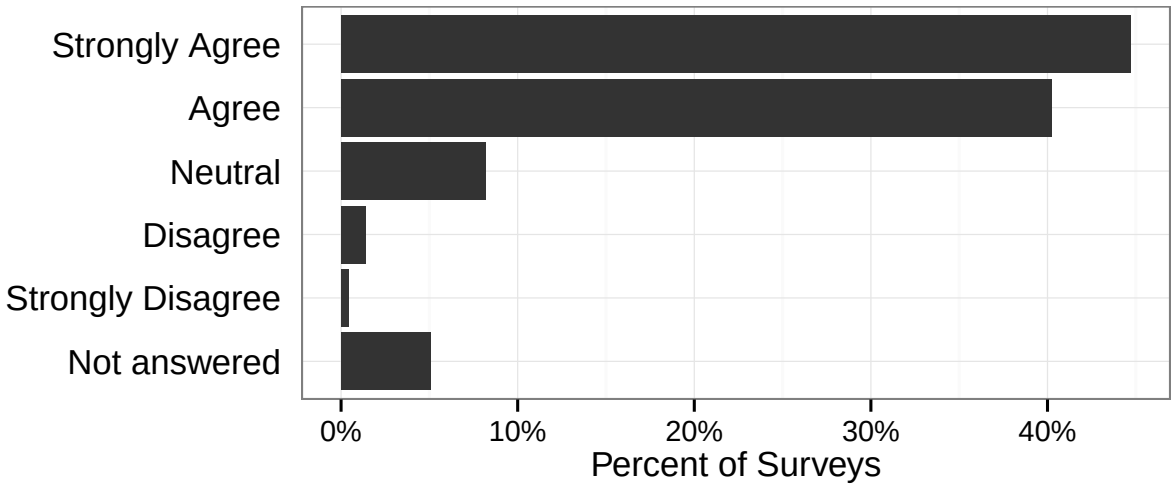
After hearing about the possible benefits and risks of the Plasma study, you believe that it is acceptable to test getting plasma before the hospital in trauma injury patients.



Mutually exclusive option	Count
Strongly Agree	318
Agree	286
Neutral	58
Disagree	10
Strongly Disagree	3
Not answered	36
Total	711

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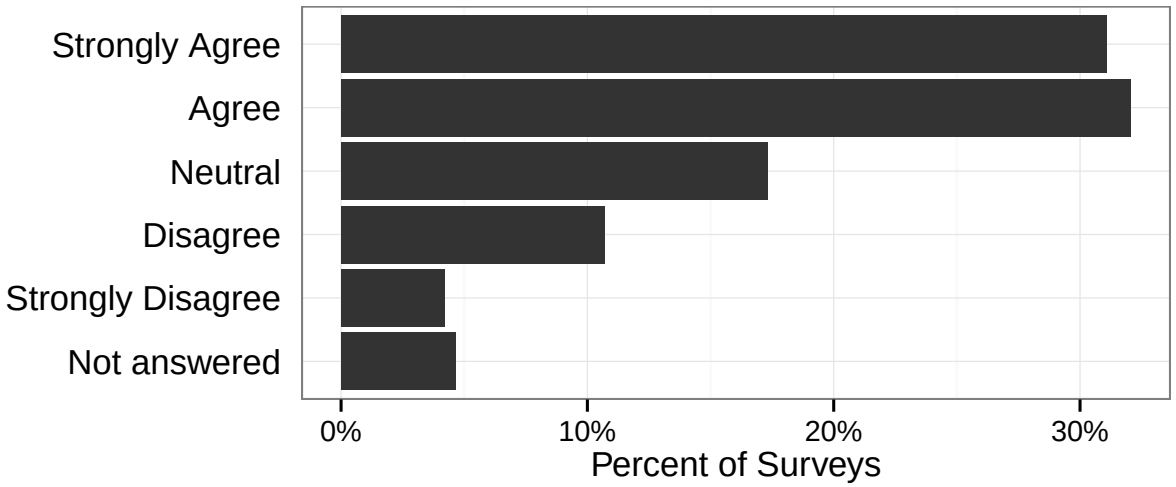
Sometimes no family member can be found to make medical decisions for patients with severe trauma injury. It is okay to include those patients in the Plasma study without consent.



Mutually exclusive option	Count
Strongly Agree	221
Agree	228
Neutral	123
Disagree	76
Strongly Disagree	30
Not answered	33
Total	711

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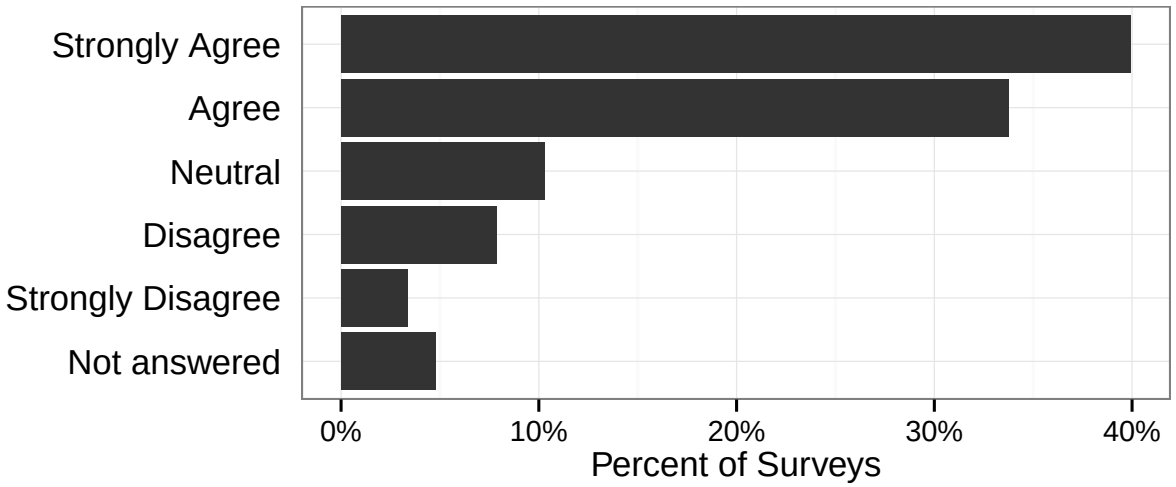
If you had a major trauma injury and no family member could be found to make decisions for you, you would be okay with being included in the Plasma study without consent.



Mutually exclusive option	Count
Strongly Agree	284
Agree	240
Neutral	73
Disagree	56
Strongly Disagree	24
Not answered	34
Total	711

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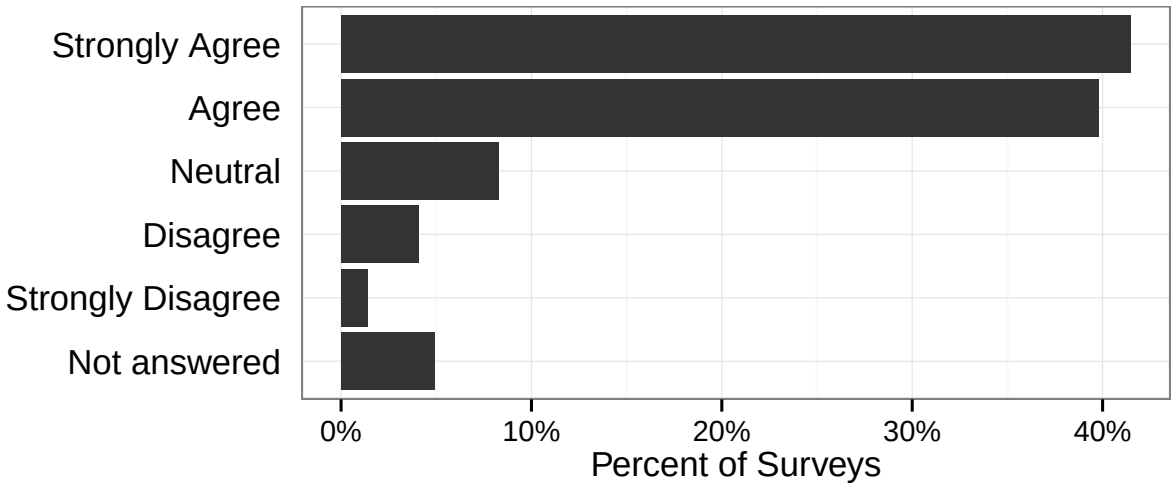
If you had a trauma injury and a family member agreed to include you in the Plasma study, you would be okay with being included.



Mutually exclusive option	Count
Strongly Agree	295
Agree	283
Neutral	59
Disagree	29
Strongly Disagree	10
Not answered	35
Total	711

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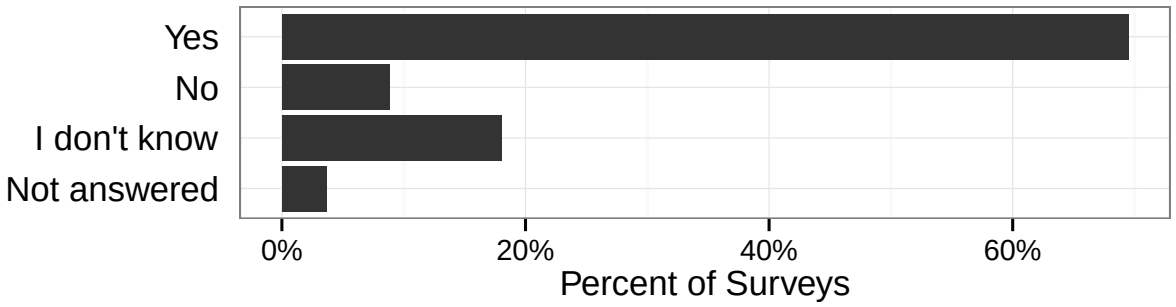
Do you think that the Plasma study researchers will seriously consider what community members like you have to say about this study before starting it?



Mutually exclusive option	Count
Yes	494
No	63
I don't know	128
Not answered	26
Total	711

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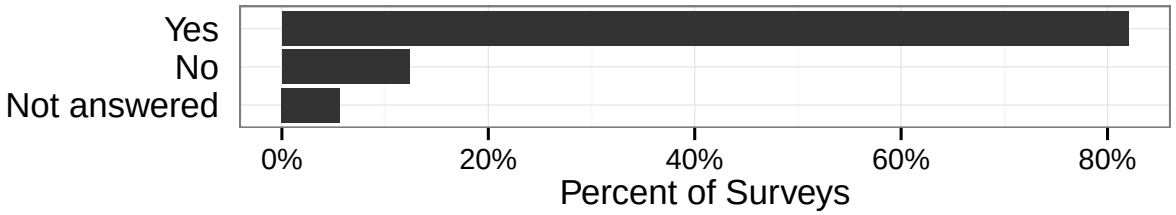
Do you feel that you have been given enough information to give your informed opinion about whether you think it is ok for researchers to do the Plasma study?



Mutually exclusive option	Count
Yes	583
No	88
Not answered	40
Total	711

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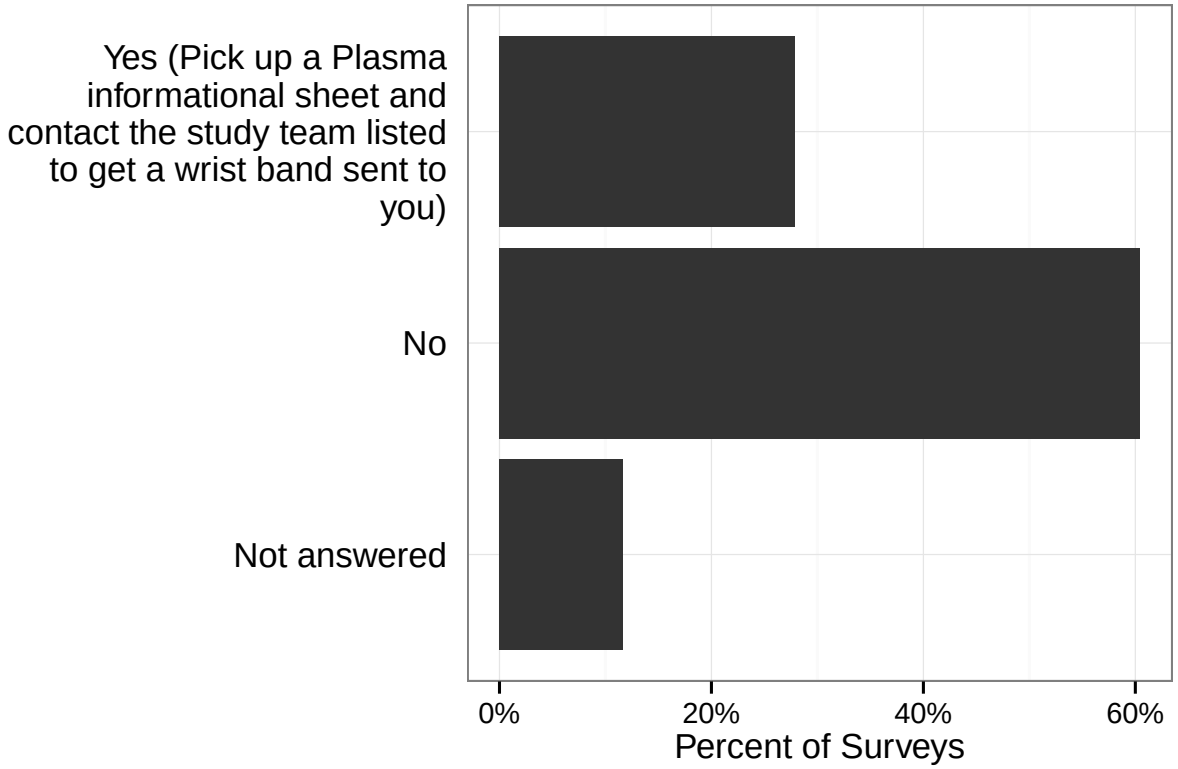
A wrist band is available ahead of time that you can wear to tell doctors that you DO NOT want to participate in this study. The wrist band says "I refuse the VCU Plasma Study." EMS personnel will not include eligible trauma patients wearing these wrist bands in the Plasma study. Do you want to wear one of these wrist bands?



Mutually exclusive option	Count
Yes (Pick up a Plasma informational sheet and contact the study team listed to get a wrist band sent to you)	198
No	430
Not answered	83
Total	711

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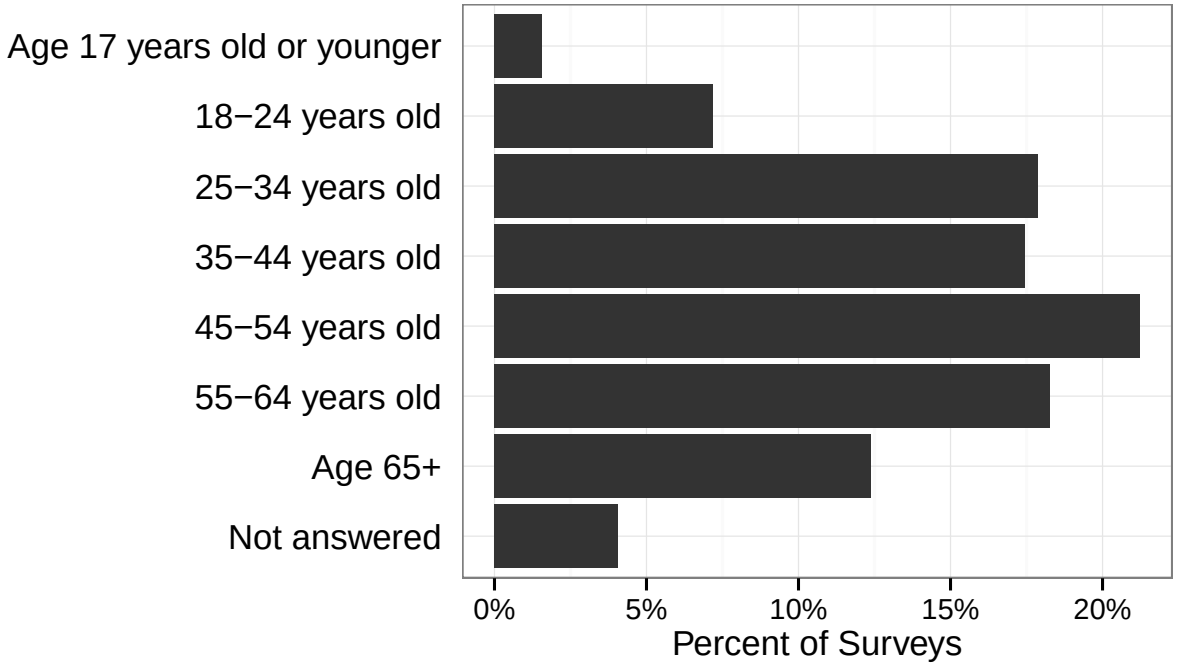
What is your age group?



Mutually exclusive option	Count
Age 17 years old or younger	11
18-24 years old	51
25-34 years old	127
35-44 years old	124
45-54 years old	151
55-64 years old	130
Age 65+	88
Not answered	29
Total	711

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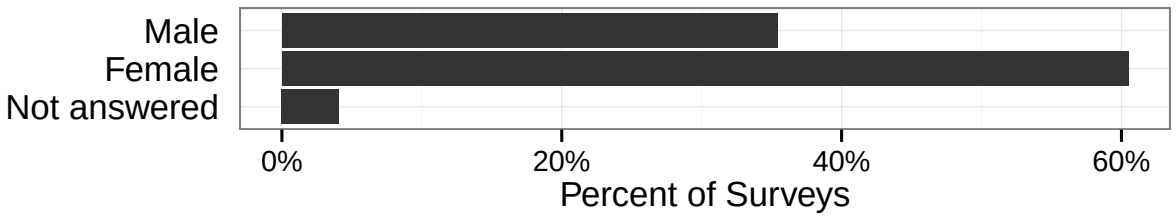
Are you:



Mutually exclusive option	Count
Male	252
Female	430
Not answered	29
Total	711

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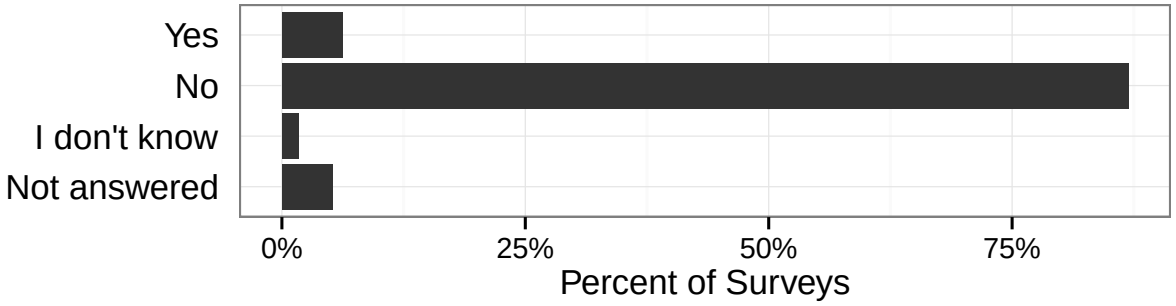
Are you Hispanic or Latino?



Mutually exclusive option	Count
Yes	44
No	618
I don't know	12
Not answered	37
Total	711

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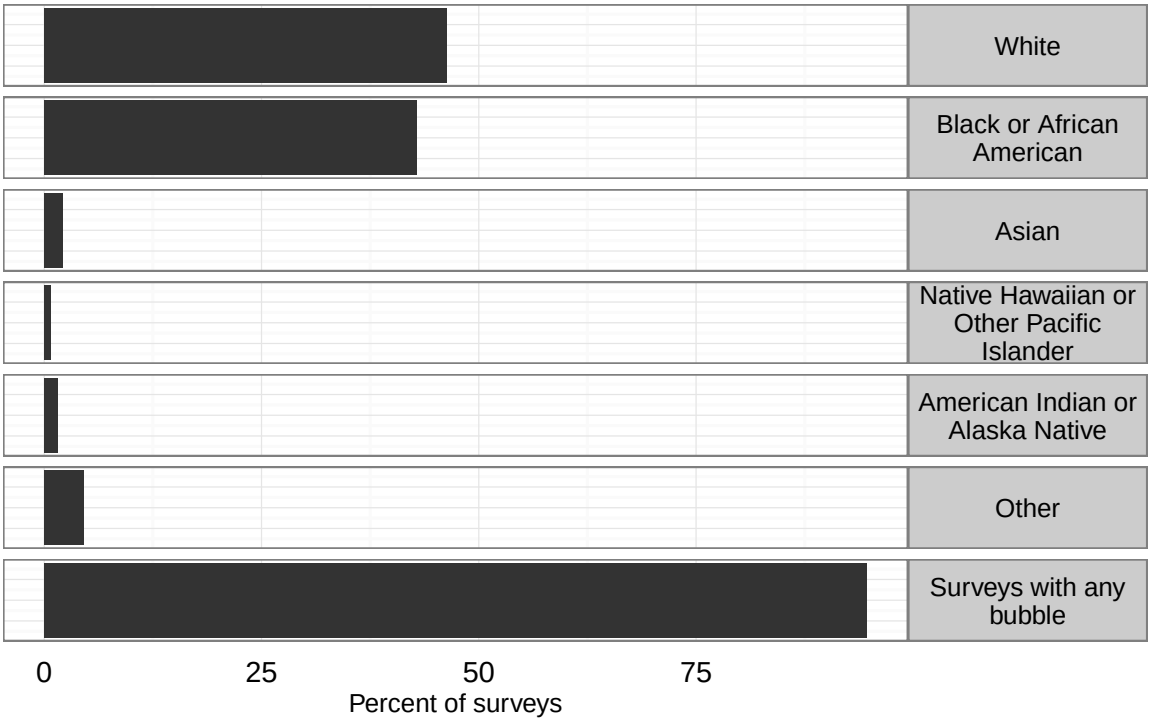
Which one or more of the following would you say is your race: (Bubble ALL that apply)



Count	All-that-apply option
329	White
305	Black or African American
15	Asian
5	Native Hawaiian or Other Pacific Islander
11	American Indian or Alaska Native
32	Other
673	Surveys with any bubble

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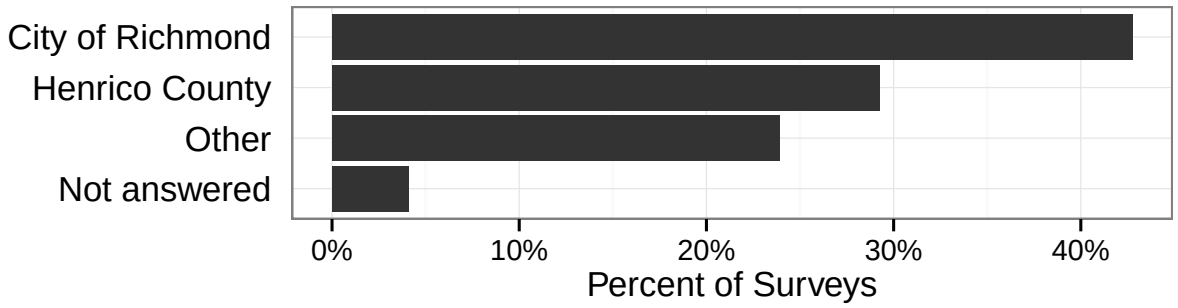
Where do you live?



Mutually exclusive option	Count
City of Richmond	304
Henrico County	208
Other	170
Not answered	29
Total	711

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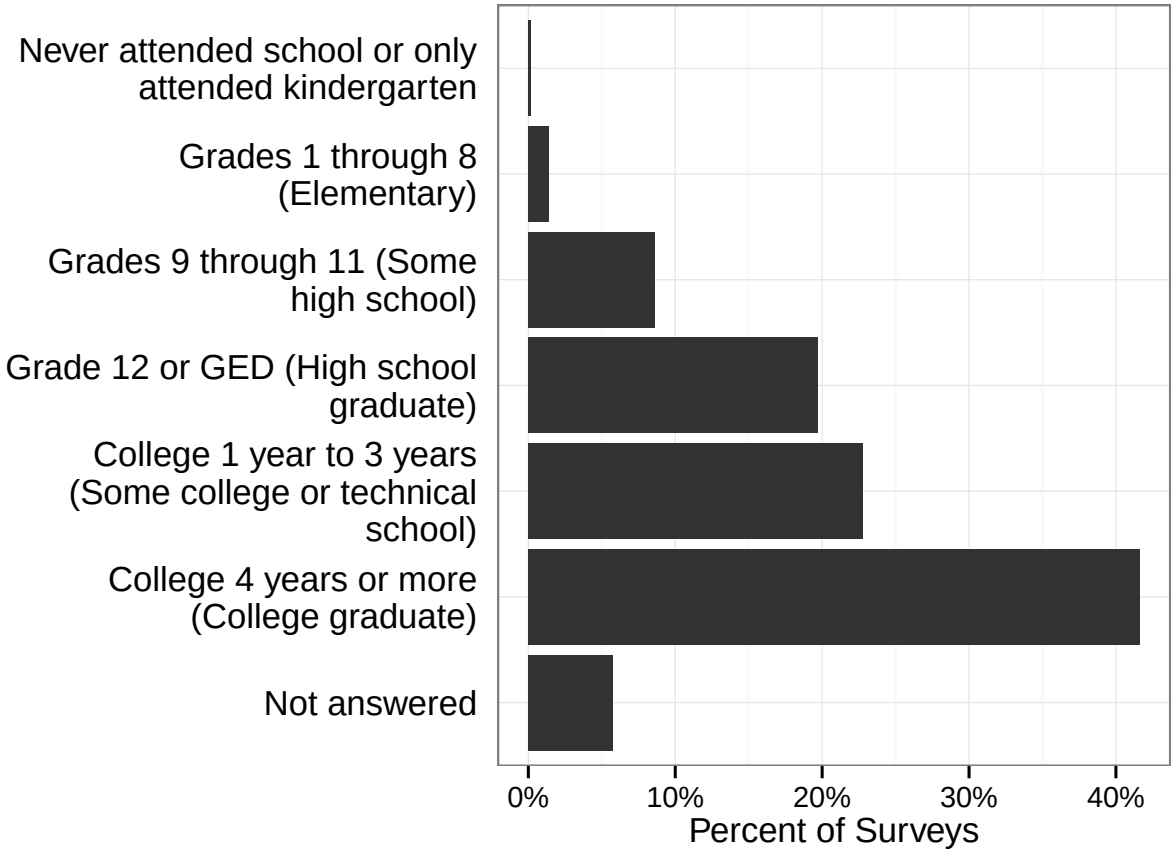
What is the highest grade or year of school you completed?



Mutually exclusive option	Count
Never attended school or only attended kindergarten	1
Grades 1 through 8 (Elementary)	10
Grades 9 through 11 (Some high school)	61
Grade 12 or GED (High school graduate)	140
College 1 year to 3 years (Some college or technical school)	162
College 4 years or more (College graduate)	296
Not answered	41
Total	711

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5 "Group" free text variables

Do you feel that you have been given enough information to give your informed opinion about whether you think it is ok for researchers to do the Plasma study?

If you answered "No", to question 12 above, what information would you still like to know?

2013-07-11	Katzen, Spiess	I need more time to think about the implications; Not everyone will trust the process
2013-09-09	Aboutanos, Katzen	Procedure whether to do it; costs involved
2013-09-09	Aboutanos, Katzen	Side effects / aides
2013-08-26	Ornato	I would like to know the percentage of the American people on TV and Dr OZ talk about this subject
2013-08-26	Ornato	Is it a time limit for this study
2013-11-20	Katzen, Spiess	More about risks and proper training. Somewhat uncomfortable with EMT's making the decision to provide blood
2013-11-20	Katzen, Spiess	More information on other localities that participated in this type of study such as survival rate
2013-11-20	Katzen, Spiess	Need greater detail about risks and benefits associated
2013-11-20	Katzen, Spiess	There are negative effects of getting plasma, but there was only one side, compared to all the possitive outcomes; I am skeptical.
2013-11-11	Katzen, Spiess	Uncertain. A longer lecture may be useful
2013-11-19	Katzen	repeat slowly
2013-11-19	Katzen	The protocol for how EMS staff will analyze a potential study patient for contraindications
2013-11-19	Katzen	how decision is made to use or not use

A wrist band is available ahead of time that you can wear to tell doctors that you DO NOT want to participate in this study. The wrist band says "I refuse the VCU Plasma Study." EMS personnel will not include eligible trauma patients wearing these wrist bands in the Plasma study. Do you want to wear one of these wrist bands?

Can you tell us why you do or else do not want to wear a wrist band?

2013-05-29	Duane	I would because of the potential to save my life and even if it doesn't the lessons/information learned could save others.
2013-05-29	Duane	I feel this is a good study with potential benefits, I would be fine to receive plasma in the community
2013-05-29	Duane	Important study - would participate
2013-05-29	Duane	I agree with the study
2013-07-11	Katzen, Spiess	Sounds beneficial in the long run and do not want to stand in the way of progress
2013-07-11	Katzen, Spiess	Wearing a wristband everyday is hard to remember.
2013-07-22	Katzen, Ornato	Potential Benefit outweighs risk
2013-07-22	Katzen, Ornato	Want to participate in the study if it is to help
2013-10-17	Spiess	I would like to be included
2013-10-17	Spiess	I think this study could be very important in giving injured people a greater chance of survival and/or better quality of life
2013-10-08	Katzen, Ornato	I want to live
2013-10-10	Katzen, Spiess	I'm ok w/ this study
2013-10-10	Katzen, Spiess	Something else to keep track of.
2013-10-10	Katzen, Spiess	want to participate
2013-09-09	Aboutanos, Katzen	I would want to be given the plasma immediately instead of waiting until I get to the hospital so I don't need to wear a bracelet to refuse the care.
2013-09-09	Aboutanos, Katzen	Don't like to wear them.
2013-09-09	Aboutanos, Katzen	I don't want to limit my own chances for possible survival.
2013-09-09	Aboutanos, Katzen	Any way to save a life is welcomed when done safely.
2013-09-09	Aboutanos, Katzen	Hospital staff might be confused
2013-08-27	Kurz	I'd be a willing participant
2013-08-26	Ornato	It my choice
2013-11-20	Katzen, Spiess	I don't object to the study and couldn't imagine wearing a wristband to plan for experiencing trauma
2013-11-20	Katzen, Spiess	I would like a decision made based on the injury at that time
2013-11-20	Katzen, Spiess	I don't think I will find myself eligible to receive plasma
2013-11-20	Katzen, Spiess	It is reminiscent of a dogtag - this type of tagging reminds me of of an internment camp.
2013-11-12	Katzen, Spiess	I believe plasma could potentially save lives.
2013-11-12	Katzen, Spiess	I need some information
2013-11-12	Katzen, Spiess	I rather be considered for the possibility than not but prefer informed consent from family
2013-11-11	Katzen, Spiess	It's a bother
2013-11-11	Katzen, Spiess	I want to participate in study
2013-11-11	Katzen, Spiess	I want to be in the study.

2013-11-11	Katzen, Spiess	I won't be here all the time.
2013-11-11	Katzen, Spiess	I want to be included in study if selected
2013-11-19	Katzen	This sounds Dumb
2013-11-19	Katzen	I may consider weraing a band if I am in the study
2013-11-19	Katzen	Not much chance of being in that situation
2013-11-19	Katzen	Don't wear any jewelry - bands
2013-11-19	Katzen	I don't even wear a wrist watch, not going to wear a bracelet
2013-11-19	Katzen	I'm ok with being included

Please provide below, any additional comments, concerns or questions you would like to share with the Plasma study team:

2013-05-29	Duane	Wasn't it true they used coconut juice for plasma substitute in WWII Pacific Theater? Obviously coconut trees not found here, but could this be another option for a non-blood/non-plasma treatment for patients? Food for thought? (pardon the pun) down the road?
2013-05-29	Duane	Nicely done presentation
2013-07-11	Katzen, Spiess	The speaker said at the beginning of his presentation that this study was important because it helps young people who have a lot to contribute to society. This is compared to studies on cancer and heart disease which affects older patients. The speaker implied that younger people have more to contribute to society and older people have less to contribute to society. I totally disagree with that discriminatory statement. I'm sure the speaker did not mean to say it that way. He needs to eliminate that comparison. Older citizens have the capacity to contribute just like younger citizens.
2013-10-08	Katzen, Ornato	Informative
2013-10-10	Katzen, Spiess	Let's do it!
2013-10-17	Spiess	Presentation was very well delivered - easy to understand
2013-10-17	Spiess	I applaud your efforts!
2013-10-10	Katzen, Spiess	Sounds like a viable study
2013-09-09	Aboutanos, Katzen	It should probably be implemented. Contact news media to get the word out. If there is also a choice, there should not be a problem.
2013-09-09	Aboutanos, Katzen	Seems like it should be done way before now.
2013-09-09	Aboutanos, Katzen	So many times a study becomes mandatory or part of standards
2013-08-27	Kurz	Not comfortable with clinical trials
2013-08-27	Kurz	Please re-evaluate the arm band as certain job requirements prevent the use of such as bracelets. For safety reasons.
2013-08-27	Kurz	Sounds like the next generation.
2013-08-26	Ornato	Who will be included in the study? All race of people or what?
2013-08-26	Ornato	I enjoyed the speaker. He did a great job. This will be a study for those who will want to join if they want to. I do not wish to join in a study thank you.
2013-08-26	Ornato	Retired Military
2013-11-20	Katzen, Spiess	I honestly tire of the MCV-VCU taking advantage of the impoverished communities of the City of Richmond while giving as little back to those communities as possible. Such lack of equality if rapacious on it's best day.
2013-11-12	Katzen, Spiess	Provide pamphlets, flyers, brochures in simpler language for the community at large
2013-11-12	Katzen, Spiess	Thanks for trying to inform the community before this goes into effect and I hope you take comments and concerns of citizens seriously.
2013-11-11	Katzen, Spiess	It seems wearing a bracelet to participate would insure ones consent. Otherwise many people are likely to be included unknowingly.
2013-11-11	Katzen, Spiess	Only wish this could happen more quickly!
2013-11-11	Katzen, Spiess	It will be hard to get info re "No participate" wristbands to the public.

2013-11-19	Katzen	Speak more slowly
2013-11-19	Katzen	Good luck

6 "Self" free text variables

Do you feel that you have been given enough information to give your informed opinion about whether you think it is ok for researchers to do the Plasma study?

If you answered "No", to question 15 above, what information would you still like to know?

2013-06-10	Han, Katzen	What side effects you might have? or health problems afterwards
2013-06-10	Han, Katzen	It is only one side of the coin that is given at this time
2013-06-10	Han, Katzen	Are there blood clot risks? How would it affect those with genetic hypercholesterolemia? Thos who take blood thinners? Nitroglycerin? Drunk from alcohol? Heparin?
2013-06-10	Han, Katzen	Because I'm not understanding whats plasms is. Don't know enough to answer
2013-06-10	Han, Katzen	I would like to research it myself - side effects...more info
2013-06-10	Han, Katzen	more time to check and read
2013-06-19	Han, Katzen	What are the risks of plasma to pt without consent and is it only random based on who carries TP
2013-06-19	Han, Katzen	What is the risk of being infected by the plasma? How are the EMT's going to be trained in the handling and giving of plasma?
2013-06-24	Han, Katzen	Questions regarding quality control of the thawed plasma itself. How will this be maintained?
2013-06-24	Han, Katzen	Side effects
2013-06-24	Han, Katzen	How do you determine pregnancy status?
2013-06-24	Han, Katzen	Further possible side effects and likelihood of them
2013-06-24	Han, Katzen	Purpose, duration, who is funding the research?
2013-08-17	Katzen	This is the wrong time/place to conduct this study!!!
2013-08-17	Katzen	How can research be done with participants consent,how can they opt out, risks of unknown, cost to community
2013-08-17	Katzen	Would like to know about the benefits and side effects; Other studies of this type that have been done
2013-07-28	Han, Katzen	more info.
2013-07-28	Han, Katzen	I need more thorough information.
2013-08-18	Han, Katzen	yes
2013-08-17	Katzen	The purpose of giving plasma
2013-08-17	Katzen	Because I don't know enough
2013-10-19	Katzen	side effects / cost / risk versus benefit
2013-07-28	Han, Katzen	If would jeopardize the safety of ones blood system
2013-08-18	Han, Katzen	What its about
2013-10-19	Katzen	more about possilbe benefits & risks
2013-10-19	Katzen	What has been the outcome of patients in the hospital? What additional training is neccesary for EMTs?
2013-10-19	Katzen	all

A wrist band is available ahead of time that you can wear to tell doctors that you DO NOT want to participate in this study. The wrist band says "I refuse the VCU Plasma Study." EMS personnel will not include eligible trauma patients wearing these wrist bands in the Plasma study. Do you want to wear one of these wrist bands?

Can you tell us why you do or else do not want to wear a wrist band?

2013-06-10	Han, Katzen	How do you plan give away to people randomly
2013-06-10	Han, Katzen	I would like to be considered if in an emergency
2013-06-10	Han, Katzen	Based on the information given to me, I am for the study
2013-06-10	Han, Katzen	I will leave it up to the providers decision
2013-06-10	Han, Katzen	I hope this works.
2013-06-10	Han, Katzen	I want to participate in this study!
2013-06-10	Han, Katzen	Job
2013-06-10	Han, Katzen	I would want to be in the study
2013-06-10	Han, Katzen	yes wear a wrist band
2013-06-10	Han, Katzen	hope not to need to come here as a trauma patient anytime soon -
2013-06-19	Han, Katzen	If I didn't want to participate it would be informational for the EMS
2013-06-19	Han, Katzen	I don't mind participating in a study that may help.
2013-06-19	Han, Katzen	Could not keep it on
2013-06-19	Han, Katzen	Not practical.
2013-06-19	Han, Katzen	I want plasma if possible
2013-06-19	Han, Katzen	Unsure at this moment.
2013-06-19	Han, Katzen	too much of a pain to wear
2013-06-19	Han, Katzen	for me this is ok.
2013-06-19	Han, Katzen	I am supportive of research
2013-06-19	Han, Katzen	leave medical decisions to professionals
2013-06-19	Han, Katzen	Don't want to refuse
2013-06-19	Han, Katzen	If it helps, do it
2013-06-19	Han, Katzen	I don't think wrist band is the way to go. Some people who don't wear the band could simply not have heard about the study.
2013-06-19	Han, Katzen	I don't mind being in the study
2013-06-19	Han, Katzen	Don't know enough about plasma study
2013-06-24	Han, Katzen	I would like to wear "I want the VCU plasma study"
2013-06-24	Han, Katzen	If it will save my life I am for doing that
2013-06-24	Han, Katzen	Because it will tell you that I am a plasma donator
2013-06-24	Han, Katzen	Never was aware of it.
2013-06-24	Han, Katzen	because it can tell what problems you have
2013-06-24	Han, Katzen	I really don't know
2013-06-24	Han, Katzen	Don't wear jewelry
2013-06-24	Han, Katzen	Inconvenient
2013-06-24	Han, Katzen	I will participate, but do you really think that everyone will know about or have access to wrist bands? Doesn't seem practical
2013-06-24	Han, Katzen	So everyone has a chance to survive
2013-06-24	Han, Katzen	It may help me. There may be a time when I can't talk.
2013-06-24	Han, Katzen	Plasma is need to save life.
2013-06-24	Han, Katzen	If it can help me

2013-06-24	Han, Katzen	Who is the study team?
2013-08-17	Katzen	Because I already donate plasma so I agree with it.
2013-08-17	Katzen	Visible to public, no privacy
2013-08-17	Katzen	inconvenient
2013-08-17	Katzen	Just don't
2013-08-17	Katzen	Do not wear jewelry, wrist bands etc -
2013-08-17	Katzen	Important to what/right care
2013-07-28	Han, Katzen	need more information
2013-07-28	Han, Katzen	my family can be found
2013-07-28	Han, Katzen	need more info
2013-07-28	Han, Katzen	would be willing to participate
2013-07-28	Han, Katzen	So Doctors can be aware and inform
2013-08-17	Katzen	so they could tell if you are allegic to any meds or who you are
2013-08-17	Katzen	It may Help You or Save Your Life
2013-08-18	Han, Katzen	So they can know my choice
2013-08-18	Han, Katzen	dont wanna be contacted
2013-08-17	Katzen	to make better opportunities for others to receive care and better benefits like more donors & meds made
2013-08-18	Han, Katzen	risk
2013-08-18	Han, Katzen	I don't wear Bands etc
2013-07-28	Han, Katzen	So that the EMS Attendants would immediately Become aware that I want the plasma instead of having to check the computer
2013-08-18	Han, Katzen	I can't keep up with wrist band I want to wear.
2013-08-18	Han, Katzen	I would wear a wrist band
2013-08-18	Han, Katzen	it good to have
2013-10-19	Katzen	I will be part of the study
2013-07-28	Han, Katzen	To be known that I'm a participate of study
2013-10-19	Katzen	hassle
2013-10-19	Katzen	Because I agree to receive plasma in this case
2013-10-19	Katzen	I wouldn't mind being enrolled
2013-10-19	Katzen	Do something like that in DMV like with organ donors
2013-10-19	Katzen	To support people
2013-10-19	Katzen	I will probably lose it
2013-10-19	Katzen	religious
2013-08-18	Han, Katzen	I believe there could be benefits
2013-08-18	Han, Katzen	Interested in what it can do for people
2013-08-18	Han, Katzen	I want all help available to me
2013-10-19	Katzen	It seems like a lot of effort for an unlikely event
2013-10-19	Katzen	I think its in order to help us on Critical Situations. I hope they do a really good job.
2013-10-19	Katzen	I believe the research is valuable.
2013-07-28	Han, Katzen	I would cause I give plasma
2013-07-28	Han, Katzen	in case of an emergency

Please provide below, any additional comments, concerns or questions you would like to share with the Plasma study team:

2013-06-10	Han, Katzen	Do it!!!
2013-06-10	Han, Katzen	I encourage the plasma study to be promoted
2013-06-10	Han, Katzen	I think that what you all are trying to do is a good thing. I wish you all all the luck
2013-06-10	Han, Katzen	no
2013-06-10	Han, Katzen	Sounds helpful to patients who may not be able to consent.
2013-06-10	Han, Katzen	Look at below
2013-06-10	Han, Katzen	Any risk of allergic reactions? Is there a risk of RBCs in plasma that may cause agglutination in patients if wrong blood type is given?
2013-06-10	Han, Katzen	Thank you to provide for the study
2013-06-10	Han, Katzen	EMS having access to computerized pt. profiles would enhance safety procedures-protocols-
2013-06-10	Han, Katzen	(1) Transfusion Reaction
2013-06-19	Han, Katzen	Need to simplify the language.
2013-06-19	Han, Katzen	Can I has da plasma?
2013-06-19	Han, Katzen	Hope it goes through!
2013-06-19	Han, Katzen	I think that it's a good idea
2013-06-19	Han, Katzen	Please explain to pts. how they were selected to participate in the study. It was not clear from the explanation whether it was random or not. Don't want people to feel left out.
2013-06-19	Han, Katzen	God Bless
2013-06-19	Han, Katzen	Support!
2013-06-19	Han, Katzen	I think the study should thoroughly examine the pros and cons
2013-06-19	Han, Katzen	A Very Important Study!!!
2013-06-19	Han, Katzen	I feel this "study" will help everyone! Please keep up the "Good" work!
2013-06-19	Han, Katzen	Let us know what you find!
2013-06-24	Han, Katzen	Keep the cost down. We are about saving lives not making money!
2013-06-24	Han, Katzen	God bless you and all you do! Thanks for my freedom!
2013-06-24	Han, Katzen	I believe this is a great study and will greatly help the community
2013-06-24	Han, Katzen	Need more study to save life.
2013-06-24	Han, Katzen	I think this is a very good research to study. I say go forward with it.
2013-08-17	Katzen	I donate plasma to help out others
2013-07-28	Han, Katzen	I think the research is needed. to find the answers to the question asked.
2013-07-28	Han, Katzen	I hope you take my opinion into consideration
2013-07-28	Han, Katzen	Thank you for the work you do
2013-07-28	Han, Katzen	Let God will be done on earth as it is in Heaven.
2013-08-18	Han, Katzen	N/A
2013-08-17	Katzen	I agree with this....
2013-08-18	Han, Katzen	N/A
2013-08-17	Katzen	none
2013-08-18	Han, Katzen	Where does the plasma come from?
2013-08-18	Han, Katzen	plasma saves lives

2013-10-19	Katzen	NA
2013-10-19	Katzen	Good luck! I hope it works!
2013-10-19	Katzen	to help all who needs
2013-10-19	Katzen	Tell people more about possilbe negative affects
2013-08-18	Han, Katzen	I think more people should learn about plasma
2013-08-18	Han, Katzen	I think that this is a good study survey
2013-10-19	Katzen	The lady at the booth is really nice.
2013-10-19	Katzen	The lady at the booth was very friendly.

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Appendix 4

5. With respect to Blood Banking:

a. Please clarify how TP with low titers of anti-B will be identified to ensure these products are issued to the ambulances.

- All thawed units will have a titer performed against reagent B-cells to ensure that the titer is not greater than 100. If the units are found to have a titer 100 or greater, they will not be used for the study and additional units will be thawed. Once testing has been completed, these units will be tagged and prepared for issue to the EMT Supervisors when needed.

- Procedure:

A. Heat seal to create a segment from the integral tube attached to the unit (if segments are not already available).
B. Remove the plasma from the segment and add to a test tube that is labeled with the unit number from the unit of plasma.
C. Mix the contents of the test tube
D. Add 1mL of normal saline to a test tube
E. Remove 10uL of saline from the test tube (leaving 990uL)
F. Remove 10uL of plasma and add to the test tube containing the saline and is labeled with the correct unit number.
G. Mix the contents of the test tube
H. Add two drops of the diluted plasma to one drop of known reagent B-cells
I. Mix
J. Spin in centrifuge for 15 seconds
K. Read for agglutination macroscopically
L. If agglutination is present, the unit will be excluded from use in the study.

b. Please clarify whether the transfusion subjects' blood group will be included in the records so it is available for later review during transfusion reaction investigations.

- All study subjects' blood typing results will be placed in their electronic medical record (Cerner Millennium) upon completion of testing. This information will be available for review by all authorized personnel.

c. Several steps in SOP: PUPTH Study Quality Control Protocols contain the abbreviation "TBD", e.g., "TBD" appears under Step A2.00 -Reading/Recording Temperatures. Please define the acronym TBD and indicate the specific procedures to be followed when reading the temperatures and when these procedures will be completed, i.e., will the procedures be completed before they are used to train EMS supervisors?

- TBD: Is defined as "to be determined"

- The temperature device will meet all FDA regulations and AABB standards for temperature monitoring of blood and blood products. This includes continuous monitoring and recording of the temperature.

- The temperature recording devices will have alarm settings that will sound if the temperature of the plasma storage device comes within 0.5 degrees Celsius of either the low or high temperature settings.

- Temperature indicators, that change color if a unit exceeds the maximum allowable temperature, will also be used alongside the temperature monitoring devices to ensure all units were continuously maintained at appropriate temperatures.

- All procedures will be finalized once the final temperature monitoring device has been purchased and validated. Part of the validation procedure is to update the applicable SOPs.

- All procedures will be completed and approved by the study principal investigator or designee prior to beginning the study.

- This section must remain TBD until such time the temperature

monitoring devices are purchased and all of the manufacturer's instructions can be incorporated into the procedure.

d. SOP: Assigning, Issuing, and Returning PUPTH Study Plasma discusses the use of a "bag tag." Please define "bag tag" and clarify why it will be used when all the information for the tie-tag is already included on the container label.

- "Bag tag" is the VCU Medical Center term for tie-tag. "Bag tag" and "tie tag" are one in the same and the information contained on each is the same.